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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/581,742 | 06/16/2000 | Frederic J. de Sauvage | P1548R1 | 4676 |

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06/17/2002

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/581,742

Applicant(s)
De Sauvage et al.

Examiner
Michael Brannock, Ph.D

Art Unit
1646



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 3, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-20, 22-32, and 34-37 is/are pending in the application
- 4a) Of the above, claim(s) 28-32 and 34-37 is/are withdrawn from consideration
- 5) ☒ Claim(s) 2, 3, 22, and 23 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 7, 10-19, and 24 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 20, and 25-27 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Application: Claims and Amendments

1. Applicant is notified that the amendments put forth in Paper 10, 4/3/02, have been entered in full.
2. Claims 1-8, 10-20, 22-32, 34-37 are pending.
3. Claims 28-32 and 34-37 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim, as set forth previously.

Specification

4. Receipt of the substitute specification is acknowledged.
5. As set forth previously, the specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 9 for example. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, 10, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth previously.

The claims require that the nucleic acid hybridize under stringent conditions. The term "stringent conditions" is confusing because it is a relative term and encompasses conditions of varying degrees of stringency - such conditions determining the bounds of the claim. It was suggested that the claim recite the actual conditions that applicant considers to be stringent, i.e., salt concentration and temperature conditions of incubations and washes.

Applicant argues that the claims have been amended to recite stringent hybridization conditions as taught in the specification. This argument has been fully considered but not deemed persuasive. First, Applicant points to page 9 for hybridization conditions, however these conditions occur at page 10 of the substitute specification. Second, the specification indicates that wash conditions are required for stringent conditions (see page 10, lines 38-39), yet claims 4 and 24 do not require any wash conditions and claim 10 requires no conditions at all.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4, 5, 7, 10-19, and 24 stand rejected under 35 U.S.C. 112, first paragraph, as set forth previously: because the specification, while being enabling for polynucleotides comprising a polynucleotide which encodes a polypeptide of having the amino acid sequence of SEQ ID NO: 2, or which encode polypeptides consisting of antigenic fragments of SEQ ID NO: 2, does not

reasonably provide enablement for polynucleotides that encode amino acid sequence variants of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that the claims have been amended to specify that the polypeptide of the subject claims bind to Gli. This argument has been fully considered but not deemed persuasive. First, in claims 1, 4, 10, 18, and 24, the amended phrase “and wherein said polypeptide binds Gli” does not refer to the polynucleotide or polypeptide that is being claimed. Second, as set forth previously, the issue is that the specification has failed to provide sufficient guidance to the highly skilled artisan to make variants of SEQ ID NO: 2 that have any particular function, and nor has the specification taught how to use the encompassed variants that have no particular function. Applicant does not appear to address this basis of the rejection.

8. Claims 1, 4, 5, 7, 10-19, and 24 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth previously.

Applicant argues that the claims have been amended to specify that the polypeptide of the subject claims bind to Gli. Thus, Applicant argues, the claims now require structural and functional limitations that are sufficiently descriptive of the genus. This argument has been fully considered but not deemed persuasive. First, in claims 1, 4, 10, 18, and 24, the amended phrase

“and wherein said polypeptide binds Gli” does not refer to the polynucleotide or polypeptide that is being claimed. Thus, this phrase appears to have very little effect on the claimed subject matter because it appears to relate to the reference sequence (SEQ ID NO: 2) and not to what is claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number AA061391, Marra et al., 03-Feb-1997, as set forth previously.

GenBank accession number AA061391 disclose an isolated nucleic acid molecule comprising DNA that is 94.9% identical to the instant SEQ ID NO: 1 from positions 189 to 463 of SEQ ID NO: 1 (see attached sequence alignment) and would therefore be expected to hybridize to the complement of the nucleic acid having the sequence of nucleotide positions from about 74 to about 1372 of SEQ ID NO: 1 and to be produced by hybridizing a test molecule under stringent conditions with a DNA molecule encoding a hSu(fu) polypeptide, e.g. SEQ ID NO: 1.

Applicant argues that the claim has been amended to require that the claimed nucleic acid is at least 1299 nucleotides, whereas the polynucleotide taught by Marra is only 275 nucleotides. This argument has been fully considered but not deemed persuasive. Marra et al. teach a

polynucleotide comprising the 275 nucleotides having sequence identity with SEQ ID NO: 1 yet this is only part of the nucleic acid taught by Marra et al. Marra et al. teach that this sequence is constructed in pBluescript (see FEATURES). pBluescript is well known to be about 3000 nucleotides in length (see Sambrook et al, page 120). Thus the nucleic acid taught by Marra et al., is greater than 1299 nucleotides.

Allowable Subject Matter

10. Claims 6, 8, 20, 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Note: the limitations placed on the claimed polynucleotides of claim 1 do not place any limitations on the claimed polypeptides of dependent claims 25-27.
11. Claims 2, 3, 22 and 23 are allowed.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sambrook et al. Molecular Cloning: A Laboratory Manual, 1989 disclose that pBluescript is about 3000 nucleotides in length.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael T Brannock whose telephone number is 703 306-5876. The examiner can normally be reached on Monday-Friday, 9:00-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703 308-6564. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

MB

June 14, 2002


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600